Health Care and the Fate of Social Europe

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Public health care systems are, in a sense, a very concrete representation of what a "social Europe" exemplifies: universality, solidarity, well-being, and inclusiveness. As Europe moved toward greater political integration in the early 1990s, the hope for many was that the principle of solidarity that informed many national health care systems could be incorporated into a European-wide schema of robust public health care. But, because the historical trajectory of these states' health care systems led to an array of different models of financing, provision, and regulation, formal integration presupposed a heroic (and arguably unattainable) degree of institutional and political reform. As the health systems of many European Union (EU) member states are a substantial component of their public sectors (and often their public culture), they are messily entangled with larger issues of national sovereignty. While the vision of a wider European health care "system" was one many member states supported at an abstract level, they resisted surrendering control of their health care systems because of fears that the "Europeanization" of health care could result in a system informed, not by solidarity, but by liberalization and the relentless pull of market forces. In consequence, little attempt was made to harmonize national health care systems directly. Member states' health care systems remain formally under national, not EU, jurisdiction, and, as such, the articulation of a "social Europe" within the domain of health policy would seem a rather limited subject for discussion.

But the role that health policy plays in the pursuit of a social Europe is more substantial, more complex, and more contingent than the narrative

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of formal competences suggests. And it is precisely the forging of health policy as a political strategy within evolving legal parameters that makes EU health policy such an enticing subject for political scientists. In this special issue of the *Journal of Health Politics, Policy and Law*, EU health policy scholars grapple with issues that illustrate the two overarching and entwined motifs that run through analyses of EU health policy. The first describes the unforeseen consequences for health care of the logical development of largely unrelated policy areas (such as fiscal governance and internal market law) through the incremental evolution of EU legislation informed, over time, by judicial interpretation and collaborative activity. This theme emphasizes the interrelationships and interdependencies of contemporary political institutions (for better or for worse).

The second motif focuses on the interaction between static institutions and dynamic political agents. The relatively young study of EU health policy is an exceptional case study of the claim that, while institutions may structure political activity, they do not prevent it. Health policy, as Scott L. Greer and Eleanor Brooks observe, illustrates "an EU long dependent on institutional creativity." The use of soft governance instruments to move beyond the limitations of formal competences is one example of the way in which the aspirations of a social Europe keep their momentum. The creative deployment of collaborative social activism is another. Social objectives may be very difficult (though not impossible) to achieve through formal legislative fiat, but the terrain of EU policy making also lends itself well to a form of guerilla warfare over social goals. Those small but determined voices in the larger rigid institutional landscape ("termites," in the words of Greer and Brooks) can use the tools of social mobilization, collective action, and discursive framing to pursue their ends with relative levels of success. In propitious times, they are able to place social issues on the political agenda and, in more inhospitable times, they try simply to limit the severity of more adverse policies.

The European Union as a Political Structure

The EU has been seen by its detractors as little more than a synonym for bureaucratic complexity. Nonetheless, its evolution has been nothing short of remarkable. Originally conceived in the wake of the destruction of World War II, the European Coal and Steel Community and then the European Economic Community were established not simply as economic unions to facilitate cross-border trade and economic growth, but more emphatically as political projects to guard against the escalation of political

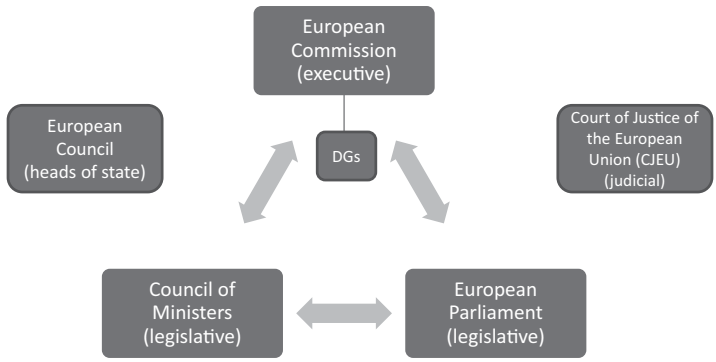

Figure 1 Key institutions of the European Union.

tensions between states. The gradual evolution of these bodies into an integrated political unit of 28 nation-states in 2019 (most notably via the 1993 Maastricht Treaty and the 2007 Lisbon Treaty) created a complex system of governance indeed, even before the intricacies of secession arose. The democratic face of the EU is the European Parliament, composed of members of the European Parliament (MEPs) elected directly by EU citizens to serve five-year terms. A second formal governance body is the Council of Ministers, comprising the relevant ministers from each member state (this is separate from the European Council, discussed below).

When considering EU health policy, however, the key institution is the European Commission, an executive body composed of one commissioner from each member state (fig. 1). This body, largely responsible for policy development (which must, in turn, be ratified by both the Council of Ministers and the European Parliament), is supported by a number of directorates-general (DGs) that focus on functional areas. One of these, DG SANTE (formerly DG SANCO), focuses on health-related issues. Another key institutional player is the Court of Justice of the European Union (CJEU), the authoritative interpreter of EU law, which must be applied in priority over national law in the national legal systems of member states in areas specified by the Treaty on the Functioning of the European Union (TFEU).

The European Council comprises the heads of state or government of all EU member states as well as the president of the European Commission and is chaired by an appointed president. While this body is not directly a decision-making body (and usually only meets four times a year), its importance rests in its ability to place issues on the political agenda. The

presidency rotates every six months according to a set schedule. Even the smallest member state has an opportunity to pull the collective gaze to issues that may be of little interest to larger states with greater national policy capacity. The Romanian presidency (January–June 2019), for example, effectively pushed for the enforcement of the European Pillar of Social Rights, leading to the possibility that rights to health care might thereby become more substantial.

To understand the political dynamics of health policy within the EU, it is useful to keep in mind three key points.

1. Formal Policy Activity at the EU Level Must Be Established on a Clear Treaty Base, and the Treaty Base for Health Care Is Very Limited

While the EU has many features of a federal system, it is nonetheless still an amalgam of autonomous states that warily guard their sovereignty against encroachment from the supranational authority of the EU. The powers of the EU have been carefully and painstakingly negotiated over a long period of time, and they are articulated within the European *acquis*, or collection of legislation, court decisions, and other documents that constitute the body of EU law, and are binding on all member states. These supranational powers are embedded in a philosophy of "subsidiarity," which assumes that decisions should be made at the most decentralized level of governance whenever possible. What this means is that any EU-level activity has to be clearly articulated and justified with reference to one of the negotiated "treaty bases" (articles within EU treaties), or to the case law that has developed around these treaty bases.

With reference to health policy, the problem is that the treaty base that explicitly recognizes the authority of the EU is very narrowly circumscribed. This formal recognition of (limited) EU authority in health care is, as Greer et al. (2019) describe, the "first face" of EU health policy. The legal base of "European" health activity is article 168 of the Treaty on the Functioning of the European Union (TFEU).[1] Article 168 focuses explicitly on public health; with a nod to the principle of subsidiarity, it also reaffirms that "the organisation and delivery of health services and medical care" is a responsibility of individual member states. Nonetheless, article 168 also invites member states "to improve the complementarity of their

1. Article 168 TFEU is the current version of article 152 EC and article 129 EU, which existed in EU treaties superseded by the TFEU.

health services in cross-border areas." Intriguingly, article 168 is also a formal endorsement of informal organization, and it encourages voluntary coordination between member states, requiring that the EU "lend support" to such collaborative activities.

The treaty base afforded by article 168 TFEU does, on the one hand, appear to "mainstream" health care across the EU by requiring a "high level of human health protection" in "the definition and implementation of all Union policies and activities." Moreover, to the extent that "public health" can potentially be interpreted quite widely to include all social determinants of health, the formal establishment of article 168 TFEU would seem to allow for a wide scope of European-level formal activity in the field of health. However, as Greer and Holly Jarman argue in this issue, "Article 168 on its own authorizes, and structures, little." While the treaty base exists in fact, the actual legal force articulated in the provision is minimal, with formal powers couched largely in the language of voluntary compliance. This does not necessarily mean a vapid and inconsequential public health presence in the European Union—merely that such measures are not dependent on article 168. As Greer and Jarman explain, public health goals can simply be more efficiently pursued using other avenues, including environmental legislation, food safety law, and workplace protection (themselves grounded in other treaty articles).

2. The EU's Preeminent Source of Power Is Regulatory Rather than Distributive

Health policy in federal and quasi-federal states is largely influenced by the capacity of a central authority to use economic incentives to achieve national adherence to a set of standards (such as Canada's use of health transfers to uphold the Canada Health Act) or to ensure national integration by redistributing health funding from healthier and wealthier regions to those with sicker and poorer demographics (as in Italy). The EU is quite singular insofar as its influence is largely regulatory.

While the EU does offer funding for redistributive purposes (generally capacity-building), these amounts are miniscule in comparison to the level of public funding provided by member states for their respective jurisdictions. (The EU's entire budget is less than 1% of the EU's GNP.) The influence of the EU is thus situated in its regulatory capacity. Because the primary raison d'être of the EU is largely that of an economic union geared to the free movement of goods and services across state borders, the focus of this authority is in fact predominantly deregulatory, and aimed at

eliminating member state laws and practices that present obstacles to free trade within the EU. An aspect of *re*-regulation has evolved concurrently, with regulatory frameworks set up at the EU level to protect the operation of the free market. On the one hand, this regulatory focus can support the objectives of advocates for a social Europe, as the use of regulatory authority has been employed to ensure certain minimum standards (e.g., a high quality of blood products, food safety, or working conditions) across the EU to prevent a race to the bottom through the reduction of standards. On the other hand, however, the regulatory apparatus of the EU exists to support the efficient functioning of the internal market, and it can undermine the ability of policy makers to maintain public health care systems based on principles of solidarity.

While the organization of national health services is formally under the clear jurisdiction of individual member states, health care within these systems consists of "goods and services" provided through various public and private mechanisms. Tension arises in cases in which the provision of health care at the national level falls afoul of EU regulations designed to buttress the effective function of free markets in "goods and services." This indirect shaping of health policy in the EU through legal mechanisms designed to support the internal market is what Greer et al. (2019) refer to as the "second face" of health policy in the EU. The most notable development in EU health policy based on the logic of the internal market has been the 2011 Cross-Border Directive on Patients' Rights. Driven largely by case law—by individuals petitioning for their right to access health services outside their respective member states—the EU was obliged to formalize a framework within which EU citizens could both provide and receive health services across member states.

Within internal market law, the provisions for free competition have posed other problems for national health care systems. Member states, as noted above, in principle enjoy full authority over their respective health care systems. Moreover, public service organizations engaged in "social activities based on solidarity" (such as public health care systems) are not directly subject to competition law. The problem is that fewer and fewer national health care systems are fully public or private: most now incorporate some aspect of private provision, generally to provide greater flexibility in the provision of health services, or to minimize public spending. Some member states have turned to such mechanisms in the wake of the 2008–10 economic downturn, as the EU's own fiscal governance mechanisms have increasingly obliged states to improve domestic financial management (see Greer and Brooks, this volume). Others, often in the newer

central European member states, must turn to the private sector to reinvigorate and rebuild struggling health systems transitioning away from the Semashko model (Sokol, this volume; see also Cayón de las Cuevas and Fierlbeck 2020).

The crux of the problem is that, once an element of a health care system is seen as engaging in an "economic" (as opposed to a "solidaristic") activity, it becomes classified as an "undertaking," and undertakings are subject to EU competition law. However, the definition of an "undertaking" is not stipulated at the treaty level; it is the product of judicial interpretation. In practice, then, it has become difficult to determine in advance whether the implementation of a mechanism, strategy, or reorganization within a member state's health system may contravene the anticompetition measures set out in articles 101 and 102 TFEU (formerly articles 81 and 82 EC). These practices can include the reference pricing of drugs, the bulk purchase of medical goods, the privatization of hospitals, the use of independently contracting health care professionals to provide public health care services, the use of public-private partnerships (P3s), the private management of public facilities, and so on (Lear, Mossialos, and Karl 2010).

One issue this raises is whether the imposition of EU competition law on national health care systems exacerbates a "liberalization bias" (Scharpf 2010), in which rules designed for the regulation of competitive markets have permeated and undermined the organization of domestic institutions (such as public health care systems) based on principles of solidarity and universalism. The design of the TFEU attempts to balance the integrative economic framework of the EU with the recognition and protection of national values and preferences by excepting undertakings that focus on "services of a general economic interest" (SGEI). These generally refer to services incorporating a "public mission" of some sort. However, the definition of SGEI is, again, not clearly or formally designated in legislation. What this lack of precision and clarity in the interpretation of "undertakings" and "SGEIs" has meant is that what is (and is not) subject to EU competition law has been determined by case law. Often consideration in these cases has been given to the principle of proportionality: even if a measure does contravene an aspect of treaty articles 101 or 102, is it nonetheless appropriate and acceptable in a given situation in order to achieve an explicit public-interest objective?

This approach may, in theory, provide a balance between economic policy at a supranational level (effective free trade within an open European market) and social policy at a national level (the protection of public institutions grounded on principles of social solidarity). But because it

depends on the gradual case-by-case investigation of the particularities of each dispute, there is little legal certainty for health policy makers (Lear, Mossialos, and Karl 2010). In practice, a body of case law often will eventually converge into a relatively clear comprehension of an issue so that, even in the absence of formal legislative direction, legal certainty evolves over time. In the case of EU competition law and health policy, however, the opposite is true, as Bruno Nikolić (in this issue) argues: the interpretation of criteria determining the application of the competition law to health care services has remained stubbornly inconsistent, leading to even greater confusion on the part of health policy makers regarding the instruments they can (and cannot) use to shape domestic health systems.

If the regulation of the EU's internal market is one important force shaping the contours of health policy in the EU (albeit indirectly), a more recent form of regulatory influence employed by the EU has been the set of fiscal governance mechanisms that emerged out of the 2008–10 economic crisis and crystalized into institutional forms between 2011 and 2013. This "third face" of EU health policy refers to the ability of the EU "to shape the fiscal policies and stances of Member States both directly, in their spending and taxing decisions, and indirectly, in the kinds of economies they shape and the risks they create" (Greer et al. 2019: 153).

The debt crisis that emerged in many EU member states (including Portugal, Ireland, Spain, Greece, and Cyprus) was consequently addressed by the European Commission, the European Central Bank, and the International Monetary Fund in a conditional manner: the delinquent states would receive a bailout, but the price of this was adherence to a strict set of fiscal governance mechanisms. Postcrisis, the EU has institutionalized a number of discrete fiscal instruments in its attempt to forestall poor economic performance in its member states (see Greer et al. 2019). One key mechanism is the "European Semester," a process permitting the European Commission to monitor the performance of member states on a consistent basis. The commission then designs country-specific recommendations (CSRs) for each member state, which attempt at a much more granular level to set out the economic challenges (and occasional successes) each country is experiencing, and the measures needed to improve performance.

This new set of fiscal instruments has now been in play for several years. Interestingly, the number of CSRs pertaining specifically to health care and long-term care have steadily increased. What have been the consequences of these governance mechanisms on health policy in the EU? As Greer and Brooks explain in this issue, two quite discrete schools of thought have presented very disparate observations. The first holds that the new fiscal

regime underscores the "liberalization bias" of the EU because of the apparent prioritization of debt and deficit reduction targets over the capacity of public institutions—like health care systems—to provide services based on solidaristic principles (i.e., access to good quality health care regardless of ability to pay). The effect of EU fiscal requirements on national health policy decisions was a clear exemplar of how the principles of economic liberalization were able to distort and undermine national institutions designed to protect social well-being.

Yet EU politics is rarely static and, as the next section describes in more detail, institutions are merely constraints; they are not destiny. The second—and more optimistic—school of thought discerns the prospect of redescribing this new fiscal governance framework in a way that provides new possibilities for a more robust social agenda. While never losing sight of the institutional hegemony enjoyed by the new fiscal governance architecture, Greer and Brooks take a closer look at the way social actors in the EU—the "termites" in their analysis—have been able to engage in strategies of mitigation, erosion, and pushback against the dominance of neoliberal interests and institutions. Placing these termites under an analytical microscope, they identify the mechanisms whereby the liberalizing forces of the recent fiscal instruments are constrained and attenuated. These strategies, argue the authors, include adding (or redefining) objectives to support a more social agenda, widening the bureaucratic landscape so that more players with broader interests are involved, and challenging or expanding the use of quantitative indicators. Indirectly and incrementally, the armature of fiscal governance is eaten away from the inside: "Its goals became broader and hazier, its participants wider and more fractious, and its data more sophisticated and harder to interpret."

3. Health Policy in the EU Importantly Is Also about Informal or "Soft" Mechanisms

The EU is a formal set of political institutions, and the study of the EU logically focuses primarily on the structure and function of these formal institutions. Yet a concentration on these formal properties alone would provide a very poor understanding of EU health policy. Much substantial health policy in the EU occurs in the wings rather than onstage. This is not to diminish the substance of EU health policy per se: like diplomacy, more is often accomplished in quiet discussions than through public fiat. The first reason for this, as noted above, is that the treaty basis for health is very limited. But the use of "soft," or voluntary and flexible, mechanisms of

collaboration is not limited to health policy in the EU; it is used extensively within the EU and supports policy making across a wide swathe of policy fields. Because national autonomy is jealously guarded by member states notwithstanding (or perhaps because of) many overarching regulatory powers exercised by Brussels, much policy making in the EU still requires political buy-in by national legislatures. This can often result in a "joint decision trap" (Scharpf 1988), in which the capacity of political actors to veto proposals can make joint decision making at a formal level quite difficult. At an informal level, however, in which actors have more input not only over the substance of proposals but also over the nature and degree of their engagement, there is more flexibility and thus often more willingness to participate. Indeed, the objective of these informal mechanisms is not simply the creation of an outcome but, more importantly, the development of long-term relationships of trust and the construction of sturdy channels of communication between member states. These relationships can make the establishment of formal EU policy building easier over the long term, and it also permits a tier of bilateral or multilateral activity between political actors who may have common concerns, without the threat of veto by others. And, as the role of the European Commission as a facilitator of voluntary collaboration between member states has been written into the TFEU, there is technically a hard requirement of the EU to support soft governance, as and when it arises at the will of member states who wish to develop an area of collaborative activity.

One familiar mechanism of soft governance is the open method of coordination, which has been the subject of much academic scrutiny (e.g., Barcevičius, Weishaupt, and Zeitlin 2014; Benz 2007; Tholoniat 2010). But there are other instruments of soft governance as well. Two articles in this volume explain in more detail how health policy in the EU uses these informal mechanisms. Dorte Sindbjerg Martinsen and Reini Schrama in this issue look at the networks of national administrative units in the EU. Using social network analysis, the authors examine two specific networks—one focusing on pharmacovigilance and one on cross-border health care—in close detail, to determine the ways in which these networks are used by member states. European administrative networks (EANs) are, in general terms, the fascia underlying the structure of the EU, serving the important function of connectivity between component units. Beyond that, their roles and competences vary considerably. We know little about the EANs involved in health policy. Not only do EANs operate away from the spotlight, they also are a relatively recent phenomenon: the considerable growth in EANs, as Martinsen and Schrama document, occurred after 2003.

The function of many informal collaborative governance mechanisms is to harmonize activity to take advantages of the EU's scale. One area of significant interest in the EU is the harmonization of several aspects of pharmaceutical policy (such as regulation, safety surveillance, and cost-effectiveness research), in which a collective European competence means less cost and administrative effort at the member state level. The first EAN examined by Martinsen and Schrama, the Pharmacovigilance Risk Assessment Committee (PRAC), was established to ensure harmonized responses to safety concerns regarding pharmaceutical products across Europe. The second, the Cross-Border Healthcare Expert Group (CBHC), was established in 2012 to assist the European Commission (EC) with the implementation of the Patients' Rights Directive. The respective EANs are important to member states in different ways, reflecting the varied influence and interest of member states in different policy areas. In general the EANs serve more technical functions aimed at better integration across the EU; however, as the authors note, involvement in EANs also serves the very political function of allowing states to better protect their interests against other member states.

Another take on the dynamics of informal harmonization in social policy within the EU is presented in this issue by Olga Löblová, who examines the dynamics underlying greater harmonization of health technology assessment (HTA) strategies within the EU. This focus is especially relevant for two reasons: first, it addresses a concern that is a high priority for member states. Pharmaceutical costs are an increasing component of national health expenditure, and with the explosion of highly priced drugs for rare diseases, spending on pharmaceuticals is set to increase dramatically (Morgan, Bathula, and Moon 2020). Second, pharmaceutical policy in the EU, as in many jurisdictions, is highly politicized because of the opposing goals of key players: profits, growth in the biotechnology sector, and access to medicines on the one hand; and patient safety, affordability for patients, and cost control for health systems on the other. Harmonized HTA is seen as an essential component to achieving the latter, but it can also be seen as a threat to those valuing the former. Moreover, HTA harmonization, despite its promise to control health care expenditure, also poses a threat to national sovereignty (and especially to the larger member states that already enjoy a well-developed HTA capacity) by potentially limiting national decisions on drug coverage. These tensions are, moreover, situated in a volatile political environment in which the integrative agenda at the elite European level clashes with the growing Euroskepticism of voters within many member states.

While the formal regulation of pharmaceuticals is largely the responsibility of the European Medicines Agency (EMA), the evaluation of the clinical and cost-effectiveness of approved drugs (which provide the evidentiary baseline for public reimbursement bodies) is formally under the jurisdiction of individual member states. The problem is that, while some states (such as France, Germany, and the UK) have institutionalized expertise in the evaluation of the effectiveness of prescribed drugs, many of the smaller and newer ones do not. Because the exercise of evaluation is very technical, it requires a cadre of highly trained experts and a budget that permits the analyses of a wide range of pharmaceutical products (and, increasingly, medical devices). By harmonizing resources and processes, states can enjoy access to a broad range of technical reports with substantially less investment.

The model of HTA in the EU is not a single agency supported by member states (which is the model that Canada, for example, uses for HTA across provincial jurisdictions). Rather, the European model rests on the sharing of technical expertise across a wide network of national HTA bodies, with the potential to establish discrete expert subgroups consisting of national representatives. Controversy arose in the EC's suggestion that these groups would provide joint clinical assessment for national reimbursement decisions, and that these assessments could not be reevaluated at the national level. This provision led to fears that the EU was "harmonizing social policy through the back door," notes Löblová, and was not widely supported at the member state level.

Löblová's analysis nicely highlights the formal versus informal dynamics underlying social integration in the EU. That the European Commission, a powerful political actor, strongly supported HTA harmonization is an intriguing challenge to the view that the wider focus on liberalization supported by the commission means a fragmented European social union more vulnerable to market forces. As the author observes, however, that the pharmaceutical companies themselves also tended to support HTA harmonization cautions against a reading that sees the EC as a supporter of a European social union per se. But if the formal support for HTA harmonization was ultimately unsuccessful, notes Löblová, the epistemic community itself continues to pursue HTA integration more incrementally and informally. It may be difficult to mobilize political support for a highly technical area at the national level, but, at the same time, integrative policy solutions can be developed more easily precisely when technocratic issues fly under the political radar.

While the legislative output of the EU (such as the 2011 Patients' Directive on Cross-Border Healthcare) tends to receive the most attention (at times developed in response to case law), the fragmented and shifting activities and relationships that take place at a more informal level are also important to understand when looking at health policy in the EU. Much policy progress occurs at an incremental pace and with limited scope. However, it is not negligible: the relationships formed by coalitions of the willing can facilitate policy experiments that, if successful, can be scaled up; more importantly, the relationships formed between member states for very specific purposes (such as networks of experts) can serve as platforms for collaborative activities in other areas. The simple establishment of channels of communication and discourse can facilitate consensus building, which, in turn, is the necessary precondition to more formal legislative activity.

EU Health Policy as a Discursive Contest

As an institutional structure, much of what the EU does can be understood in functional terms: what it does, and how it does it. But it is also the site of a more normative discussion about how legal and political institutions ought to be structured: to what end does an activity occur? While the EU was established originally as an economic union, many supporters of a more integrated European entity also saw the potential for an enhanced social union in which competitive processes would be balanced by a more solidaristic approach to well-being. The more optimistic hoped for a greater redistribution of health care resources across state borders; the more realistic were content to focus on improvements that could be established through regulatory instruments.

And improvements to the social agenda there have been. Despite health care systems being clearly subject to the jurisdiction of member states alone, the fact that health conditions are often influenced by social determinants outside the formal scope of health systems means that the improvement in health for EU citizens can be approached strategically in a number of ways. The regulatory framework of the EU does present evidence that social goals can be achieved through other treaty bases (success stories here include consumer protection, environmental regulations, and working conditions). That such measures are often supported on the grounds that they protect competitiveness does not limit their effectiveness.

If regulatory approaches are one instrument that advocates of a social Europe employ, rights-based approaches are another. These rights are

usually articulated within a specific discursive context addressing what it is that individuals in member states should be able to expect qua their status as citizens of the EU. To an extent, the discussion of "health rights" is simply a proclamation about values and is articulated in the communications that arise in response to internal market provisions that pose potential threats to solidaristic health care systems (the 2006 "Council Conclusions on Common Values and Principles in European Union Health Systems" and the 2014 commission communication on "Effective, Accessible and Resilient Health Systems" are two examples). But the articulation of European health rights is not merely a symbolic statement, and the recent development of the European *acquis* arguably gives it more bite.

There are three key documents outlining current health rights in the EU. The issue, of course, is in what form, and to what extent, the fairly vague provisions of these documents can be imposed on the governments of member states. The European Social Charter ([1961] 1996), for example, requires states to "undertake, either directly or in cooperation with public or private organisations, to take appropriate measures" to design instruments to "remove as far as possible the causes of ill-health." As not all member states have ratified all sections of the revised charter, the provisions are not well incorporated into the case law of the CJEU. The Charter of Fundamental Rights, which became part of EU law under the Lisbon Treaty in 2009, is formally justiciable and applies both at the member state level ("Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices") and at the EU level ("A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities"). There is, however, some debate regarding the extent to which provisions of the charter are principles, rather than rights, which may dissuade the CJEU from imposing positive duties on political institutions (De Schutter 2018). The third document, the European Pillar of Social Rights, established in 2017, states that "everyone has the right to timely access to affordable, preventive and curative health care of good quality." While this document is, again, a formal part of the EU *acquis*, there is some question about how directly enforceable it is (for a more detailed discussion of the European Pillar of Social Rights, see Vanhercke, Sabato, and Ghailani 2018).

As case law is still evolving in this area, it is difficult to evaluate the impact of a "right to health care" in individual cases. More important, however, is the effect of a formal health care right on larger EU policies. In this context, these documents serve as an indeterminate but not ineffectual

counterbalance to the fiscal mechanisms used to achieve the EU's macroeconomic objectives. As Greer and Brooks describe in this issue, the most severe effects of the EU's semestering process have been mitigated by the formal recognition that access to "health care of good quality" cannot be compromised by the budgetary requirements imposed on member states by the EC. In this way, the articulation of EU health care rights has had more value in the political sphere than in the judicial one.

A third locus for the tension between economic and social Europe arises in the discussion about democratic processes. While much interest in the future of social Europe is focused on the potential outcomes—better health care for individuals or states—a separate issue concerns the process and terms of defining health policy in the EU. More formally stated, rather than a simple matter of output legitimacy (what outcomes are facilitated?), EU health policy is also informed by questions of input legitimacy (who gets to have a voice?) and throughput legitimacy (through what processes?) (Schmidt 2013). As the EU does not enjoy the more organic forms of historical and cultural legitimacy enjoyed by member states, it has "been particularly attentive to and engaged in developing legitimacy for itself and its policies" (Greer et al. 2019: 53).

The discourse about "insiders" and "outsiders" in the EU is critical because it informs perceptions of the legitimacy of EU institutions more widely, underscoring, as Löblovà observes, the tension between the "integrative agenda" of many European elites and "the growing Euroskepticism of European voters." Two contributors to this volume address the complex dynamics of democratic legitimacy within the sphere of EU health policy. The first investigates the way that EU institutions and processes have affected health care in the Central and Eastern European (CEE) member states. As Tomislav Sokol explains, the effects of EU institutions on CEE health systems are both complex and contradictory. On the one hand, his empirical data show that there has been a general improvement in access to health care in CEE since accession to the EU due, in large part, to the improved economic performance of these states. On the other hand, the EU's fiscal governance mechanisms have had considerable negative effects on the health care systems of CEE member states. Following the 2008–10 financial crisis, the excessive deficits of several states triggered fiscal reviews that led to expenditure controls at the national level, usually by freezing public sector spending and shifting costs to patients. Yet, observes Sokol, the effect of EU fiscal mechanisms is not unidirectional. As Greer and Brooks point out in their own contribution, the country-specific recommendations issued by the EC to some CEE states have increasingly been

taking into account wider social objectives: Sokol corroborates this by noting that some CEE member states have been urged to increase access to health care services (by, e.g., reducing out-of-pocket payments) in states where public health care funding is below the EU average. For most CEE member states, however, the increased ability of citizens to access affordable health care since accession to the EU has been seriously offset by fiscal governance measures imposed after 2008.

A deeper structural issue is a consequence of the very mobility that has facilitated economic growth in CEE. Highly trained health care professionals can easily leave CEE for higher-income member states, leaving CEE states with a serious shortage of health care workers in many areas. Yet even here the dynamics are not simple: in a small number of the higher-income CEE states, argues Sokol, open mobility has resulted in positive improvements to the health care system (better infrastructure, improved working conditions), as the porous borders have obliged states to direct more funding into their health care systems to retain the cadre of professional workers. Nonetheless, the exodus of CEE health care professionals exacerbates health care disparities and aggravates the perception of CEE inhabitants that they are "second tier" citizens. To bolster the legitimacy of EU institutions in the CEE, argues Sokol, those member states who have benefitted most from the EU's open borders should be increasing, rather than reducing, funds dedicated to cohesion policy.

Another discussion of the manifestation of the tension between "insiders" and "outsiders" focuses not simply on the effects of EU institutions on health care provision but, more intricately, on the processes and rules that permit individuals to influence the institutions that shape health policy around them. The secession of the United Kingdom from the European Union, argue Tamara Hervey et al. in this issue, poses an interesting case study of the way in which laws structure inclusion and exclusion. To the extent that the UK's decision to step away from the EU has resulted in health externalities for identifiable groups, these "Brexternalities" affect the legitimacy of the strategies of secession. "Outsiders" are those who did not have a formal voice in the UK's decision to leave the EU, and who have no voice in the terms on which the UK will leave, yet will nonetheless experience the impact of the UK's secession from the EU. Given that the legitimacy of the EU is grounded at least partially on the principle of inclusiveness, argue the authors, an obligation arises to protect these outsiders "from a decision made by the 'insider' population of the UK who were entitled to vote in the referendum, and from the acts of the 'insider' UK governments."

Conclusion

The evolution of health care governance in the European Union—much like the transformation of the European Union itself—has been quite remarkable during the past three decades. But it has also (like the wider politics of the European Union) been a discussion couched in highly technical details and informed by the domestic contexts of the political actors. While the dynamics of European Union health policy have thus not been easily accessible, they are nonetheless a useful intellectual touchstone to those interested in health politics, policy, and law because they tangibly incorporate three key challenges that arguably inform all contemporary health care systems.

The first juxtaposes the speed of modern technological transformation with the stasis of stable, concrete, and predictable governance structures. The development of what is possible technically within the fields of information technology (algorithms based on large data sets, the collection of health information from individuals via smart devices, the ability to communicate remotely) and biochemistry (the rapid expansion of pharmaceutical compounds and medical devices, the growth of genomic approaches to medicine) sits awkwardly on formal governance mechanisms that provide constancy over time, but can be poorly situated to address rapidly evolving technologies (e.g., the regulation of medical devices).

The second tension is the result of an emphasis on economic growth focusing on globalized trade relationships. The ability to trade freely and widely depends on the development of technical specifications and legal requirements that demand uniformity and standardization. An open and competitive global market also requires rules that do not privilege local actors over more remote ones. At the same time, however, health care systems have generally evolved historically into specific entities that have been responsive to local needs, norms, preferences, and capacity. Individuals are not purely mechanistic creatures, and an understanding of unique cultural or socioeconomic contexts can be essential in facilitating good health. The economic imperative to broaden the geographic base of political relationships thus fits uneasily with health care systems that are a product of, and responsive to, local communities.

The third tension addresses the normative foundational principles underlying health care systems. The contours of this tension are not new; the articulation of a competitive, individualistic ethos versus a redistributive and solidaristic one is perhaps as old as the idea of health care as a system itself. Nonetheless, the two phenomena noted above have exacerbated the

debate about the extent to which health care should (or should not) be viewed as a commodity. Given the sheer volume of treatments and services now available—even compared to 40 or 50 years ago, when the governance structures of many health systems crystalized into their current forms—it is increasingly impossible to provide full public coverage of all therapeutic services. The discussion, even (or especially) in solidaristic states, of who is entitled to what, and on which terms, has become heightened. Likewise, when localized health care systems are integrated into a wider political community, the debate about who should enjoy what kinds of services (and where) intensifies.

EU relations in the face of the 2019 pandemic highlighted all three of these tensions. The institutions of the European Union were not designed to respond quickly to sudden crises (this became evident both during the 2008 recession and in response to the issue of increased migration). The first reaction to the spread of the novel coronavirus throughout Europe was a series of border closures and export restrictions, followed by an acrimonious debate between member states over the extent to which economic assistance should be distributed to nations most in need (and the conditions under which such transfers should be made). Nonetheless, as one EU commissioner explained, this was the natural human response: the first instinct was to fend for oneself, followed by the understanding that cooperation can provide better results. And, notwithstanding the fractious initial responses, the EU has gradually and systematically "deployed its full panoply" of instruments to address the COVID-19 crisis. These have included direct grants, tax advantages, direct public loans, public loan guarantees, safeguards for banks, and export credit insurance (Dimitrakopoulos and Lalis 2020). The EU's Cohesion Funds and Solidarity Funds are being directed to address public health measures. The Joint Procurement initiative established in the wake of the H1N1 pandemic is a mechanism that can enable the efficient deployment of vaccines and equipment across member states. European data protection rules provide an armature that balances effective contact tracing capacity with privacy rights. When the full array of the possible benefits of EU membership are set out, the advantages of dealing with major crises within a large political union become much clearer.

It is eminently possible that the health and economic challenges generated by COVID-19 may strain the frayed political bonds of the EU beyond repair. On the other hand, should member states be able to negotiate a program of debt relief, there may be an unprecedented level of economic distribution across the EU. Just as strikingly, the pandemic has placed the

concept of a "European health care system" squarely back on the political agenda. As Germany gained the presidency of the European Council at the height of the pandemic, the German chancellor stated that "the idea of an efficient European health care system for all member states" will be the focus of its six-month term (Reuters 2020). To the extent that major policy change is tempered in the fire of political crisis, the COVID-19 pandemic could potentially lead to a stronger social Europe.

This collection of articles, originally workshopped in Copenhagen in 2019 under the aegis of the Jean Monnet Network in Health Law and Policy, provides more detailed insights into the ways in which these tensions are played out within the EU. The broad directional sweep of EU health policy at a formal level can be discerned by examining the formal communications of member states and EU institutions, but the tensions and complexities that describe the evolution of EU health policy can only truly be understood by examining the smaller currents and eddies that swirl within it. In the end, a deeper comprehension of EU health policy has direct relevance well beyond the EU, as it offers both cautions about what can be expected politically in navigating contemporary health policy, and strategies for negotiating the complex technical, political, and economic context of the 21st century.

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